



## INFORMATION DISCLOSURE STATEMENT

Applicant : Weber, et al.  
 App. No : 10/828,795  
 Filed : April 21, 2004  
 For : COMPOSITIONS FOR AFFECTING WEIGHT LOSS  
 Examiner : Zhang, Nancy  
 Art Unit : 1614

## CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

October 3, 2006

(Date)

*Joseph J. Mallon*  
Joseph J. Mallon, Reg. No. 39,287

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 121 references to be considered by the Examiner. Also enclosed are 71 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the mailing date of a final action and before the mailing of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

10/10/2006 CNGUYEN2 00000001 10828795  
01 FC:1806 180.00 OP

Dated: 10/3/06

By: Joseph J. Mallon  
Joseph J. Mallon  
Registration No. 39,287  
Attorney of Record  
Customer No. 20,995  
(619) 235-8550



OCT 06 2006	Application No.	10/828,795	
INFORMATION DISCLOSURE		Filing Date	April 21, 2004
STATEMENT BY APPLICANT		First Named Inventor	Weber, et al.
(Multiple sheets used when necessary)		Art Unit	1614
SHEET 1 OF 6	Examiner	Zhang, Nancy	
	Attorney Docket No.	OREX.001A	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	3,819,706	06-25-1974	Mehta, N.	
	2	3,885,046	05-20-1975	Mehta, N.	
	3	4,089,855	05-16-1978	Chatterjie et al.	
	4	4,172,896	10-30-1979	Uno, et al.	
	5	4,513,006	04-23-1985	Maryanoff, et al.	
	6	4,673,679	06-16-1987	Aungst et al.	
	7	4,689,332	08-25-1987	McLaughlin et al.	
	8	5,358,970	10-25-1994	Ruff, et al.	
	9	5,426,112	06-20-1995	Zagon, et al.	
	10	5,427,798	06-27-1995	Ludwig, et al.	
	11	5,541,231	07-30-1996	Ruff, et al.	
	12	5,719,197	02-17-1998	Kanios et al.	
	13	5,731,000	03-24-1998	Ruff, et al.	
	14	5,763,493	06-09-1998	Ruff, et al.	
	15	6,004,970	12-21-1999	O'Malley, et al.	
	16	6,071,537	06-06-2000	Shank	
	17	6,071,918	06-06-2000	Cook	
	18	6,110,973	08-29-2000	Young, James	
	19	6,191,117	02-20-2001	Kozachuk	
	20	6,262,049	07-17-2001	Coffin et al.	
	21	6,323,236	11-27-2001	McElroy	
	22	6,344,474	02-05-2002	Maruani et al.	
	23	6,437,147	08-20-2002	Anderson, et al.	
	24	6,441,038	08-27-2002	Cook	
	25	6,506,799	01-14-2003	Dasseux	
	26	6,541,478	04-01-2003	O'Malley, et al.	
	27	6,548,551	04-15-2003	Hinz	
	28	6,569,449	05-27-2003	Stinchcomb et al.	
	29	5,713,488	03-30-2004	Sadee, et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application No.	10/828,795
		Filing Date	April 21, 2004
		First Named Inventor	Weber, et al.
		Art Unit	1614
(Multiple sheets used when necessary)		Examiner	Zhang, Nancy
SHEET 2 OF 6		Attorney Docket No.	OREX.001A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number <i>Number - Kind Code (if known)</i> Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	2001-0025038	09-27-2001	Coffin, et al.	
	31	2003-0144174	07-31-2003	Brenna et al.	
	32	2003-0055008	03-20-2003	Marcotte, David B.	
	33	2004-0002462	01-01-2004	Najarian	
	34	2004-0029941	02-12-2004	Jennings	
	35	2004-0033965	02-19-2004	Gadde, et al.	
	36	2004-0106576	06-03-2004	Jerussi, et al.	
	37	2004-0198668	10-07-2004	Gadde, et al.	
	38	2005-0026986	02-05-2003	Maruani et al.	
	39	2005-0137144	06-23-2005	Gadde, et al.	
	40	2005-0143322	06-30-2005	Gadde, et al.	
	41	2005-0154002	07-14-2005	Crooks, et al.	
	42	2005-0181070	08-18-2005	Gadde et al.	
	43	2005-0215552	09-29-2005	Gadde et al.	
	44	2005-0277579	12-15-2005	Krishnano, et al.	
	45	2006-0009514	01-12-2006	Gadde et al.	
	46	2006-0058293	03-16-2006	Weber, et al.	
	47	2006-0079501	04-13-2006	Gadde et al.	
	48	2006-0100205	05-11-2006	Weber, et al.	
	49	2006-0142290	06-29-2006	Weber, et al.	
	50	2006-0160750	07-20-2006	Gadde et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials	Cite No.	Foreign Patent Document <i>Country Code-Number-Kind Code</i> Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	51	WO 00/76493	12-21-2000	Najarian	
	52	WO 03/013524	02-20-2003	Glober Hillel	
	53	WO 03/092682	11-13-2003	Elan Pharma	
	54	WO 03/097046	11-17-2003	Gadde, et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application No.	10/828,795
		Filing Date	April 21, 2004
		First Named Inventor	Weber, et al.
		Art Unit	1614
(Multiple sheets used when necessary)		Examiner	Zhang, Nancy
SHEET 3 OF 6		Attorney Docket No.	OREX.001A

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No.	Foreign Patent Document <i>Country Code-Number-Kind Code</i> Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	55	WO 04/009015	01-29-2004	Merck & Co.		
	56	WO 04/096201	11-11-2004	Weber et al.		
	57	WO 05/049043	06-02-2005	Ortho-McNeil		
	58	WO 96/09047	03-28-1996	Du Pont Merck Pharma		
	59	EP 0 442 769 A2	08-21-1991	Guillaument		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	60	"A Novel Twist on Binge Eating Treatment" Primary Psychiatry; 6(10) 24-29 (1999)	
	61	ANDERSON, et al. Bupropion SR enhances weight loss" Obesity R., Vol. 10, N. 7, 2002, pp. 633-641, XP002351373	
	62	Altman and Bland. "Standard Deviations and Standard Errors," BMJ; 2005:331:903.	
	63	Appolinario et al. "Pharmacological Approaches in the Treatment of Binge Eating Disorder." Current Drug Targets; 5:301-307 (2004).	
	64	Asconape. "Some Common Issues in the Use of Antiepileptic Drugs." Seminars in Neurology; 22(1):27-39 (2002).	
	65	ATKINSON, "Clinical Guidelines on the identification, Evaluation, and pharmacologic treatment of obesity in Adults, Online, 07-25-2003, URL: <a href="http://www.endotext.org.obesity/obesity15b/obesity15b.htm">http://www.endotext.org.obesity/obesity15b/obesity15b.htm</a> .	
	66	Ayala, "Weight Loss Associated With the Administration of Zonisamide", AES Proceedings, Epilepsia 41(Suppl. 7) :99 (2000) -No.2.041	
	67	Ayala et al, "Weight Loss Associated With the Administration of Zonisamide", A Compendium of Posters and Platform Sessions for ZONEGRAN™ and DIASTAT®, Presented at the Annual Meeting 2000 of the American Epilepsy Society, December 1-6, 2000, Los Angeles, California	
	68	BEELEN, et al. "Asymptomatic QTc prolongation associated with quetiapine fumarate overdose in a patient being treated with risperidone" Human & Experimental Toxicology 92001) 20, 215-219.	
	69	CALABRESE, et al. Letters to the Editors, "Lamotrigine and Clozapine for Bipolar Disorder" American J. of Psychiatry, vol. 157 9, September 2000, 1523	
	70	CARLSEN, et al. "Evidence for dissociation of insulin-and weight-reducing effects of metformin in non-diabetic male patients with coronary heart disease" Diabetes Research and Clinical Practice Amsterdam, vol. 39, No. 1, Jan. 1998, pp. 47-54.	
	71	CHEN, et al. "Synergistic Effects of Cannabiniod inverse agonist AM251 and opioid antagonist nalmefene on food intake" Brain Res. Vol. 999, January 2004, pp. 22-230	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application No.	10/828,795
		Filing Date	April 21, 2004
		First Named Inventor	Weber, et al.
		Art Unit	1614
(Multiple sheets used when necessary)		Examiner	Zhang, Nancy
SHEET 4 OF 6		Attorney Docket No.	OREX.001A

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>1</sup>
	72	CHENGAPPA, et al. "Changes in body Weight and Body mass index among psychiatric patients receiving lithium, valproate, or topiramate: an open-label, nonrandomized chart review" Clinical Therapeutics, 24 (10) 1576-1584		
	73	DEMBOWSKI, et al. "Successful Antimanic Treatment and Mood Stabilization with Lamotrigine, Clozapine, and Valproate in a Bipolar Patient after Lithium-induced Cerebellar Deterioration" Letter Pharmacopsychiatry, 2003; 36 83-86.		
	74	Diagnostic and Statistical Manual of Mental Disorders. 4th Edition, Text Revision, p.583-595 (2000).		
	75	DURSEN, et al., "Clozapine Plus Lamotrigine in Treatment-Resistant Schizophrenia, Arch Gen Psychiatry Vol. 56, Oct. 1999, 950-951.		
	76	DURSUN, et al. "Lamotrigine-Clozapine Combination in Refractory Schizophrenia: Three Cases" J. Neuropsychiatry Clin. Neuroscience, 14:1, Winter 2002, 86		
	77	DURSUN, et al. "Augmenting Antipsychotic treatment with Lamotrigine or topiramate in patients with treatment-resistant Schizophrenia: a naturalistic case-series outcome study" Journal of Psychopharmacology 15(4) 2001- 297-301.		
	78	DURSUN, et al., "Psychopharmacology for the Clinician Psychopharmacologie Pratiqu" Journal of Psychiatry Neuroscience, vol. 26 No. 2, 2001, 168		
	79	DURSUN, et al. "Accelerated Weight Loss After Treating Refractory Depression with Fluoxetine Puls Topiramate: Possible Mechanism of Action" Canadian Journal of Psychiatry, vol. 46, No. 3 April, 2001, pp. 287-288		
.	80	Faught et al. "Randomized Controlled Trial of Zonisamide for the Treatment of Refractory Partial-Onset Seizures." Neurology; 57(10):1774-1779 (2001).		
	81	GADDE, et al. , "Zonisamide for Weight Loss in Obese Adults - A Randomized Controlled Trial" JAMA 289 (14): 1820-1825 (2003)		
	82	GADDE, et al. "Bupropion for Weight Loss: An Investigation of Efficacy and Tolerance in Overweight and Obese Women" Obesity Research 9 (9): 544:551 (2001)		
	83	Gadde et al, "Randomized Controlled Trial of Zonisamide for Treating Obesity", American Epilepsy Society, <a href="http://164.109.45.39/submission/aes/status/..\\preview.full.asp?presid=2%2E258">http://164.109.45.39/submission/aes/status/..\\preview.full.asp?presid=2%2E258</a> , September 11, 2002		
	84	Gadde et al, "Randomized Trial of Weight Loss Efficacy of Zonisamide", No. 304, 26(Suppl. 1), August 2002, International Journal of Obesity and Related Metabolic Disorders, Journal of the International Association for the Study of Obesity, Ninth International Congress on Obesity, Sao Paulo, Brazil, August 24-29, 2002		
	85	Gadde et al, "Zonisamide in Obesity: A 16-Week Randomized Trial", No. NR473, New Research, American Psychiatric Association 2002 Annual Meeting, May 18-23, 2002, Philadelphia, Pennsylvania		
	86	Gadde and Logue, "Bupropion Sustained Release in Obesity: A Randomized Double-Blind, Placebo-Controlled Study", No. NR634, New Research Program & Abstracts, American Psychiatric Association, 1999 Annual Meeting, The Clinician, May 15-20, 1999, Washington, D.C.		
	87	Gadde et al. Inpharma; 1383(84):9 (2003).		

Examiner Signature	Date Considered
--------------------	-----------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application No.	10/828,795
		Filing Date	April 21, 2004
		First Named Inventor	Weber, et al.
		Art Unit	1614
(Multiple sheets used when necessary)		Examiner	Zhang, Nancy
SHEET 5 OF 6		Attorney Docket No.	OREX.001A

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	88	GATLEY, et al. "European Journal of Pharmacology, 307:331-338 (1996)	
	89	Ginsberg and Sussman, "Effects of Mood Stabilizers on Weight", Primary Psychiatry 7(5):49-58 (2000)	
	90	Grady, "Quest for Weight-Loss Drug Takes an Unusual Turn", The New York Times – Health, www.nytimes.com, March 15, 2003	
	91	GORDON, et al. "Mood Stabilization and Weight Loss with Topiramate" American Journal of Psychiatry, American Psychiatric Association, Washington D.C. Vol. 156, No. 6, June 1999, pp. 968-969	
	92	Harrison's Principles of Internal Medicine. Eleventh Edition, McGraw-Hill Book Company, p1921-1930 (1987).	
	93	Jallon et al. Drug Safety; 24(13):969-978 (2004).	
	94	KIPTOO, et al. "Enhancement of Transdermal delivery or 6-B-naltrexol via a codrug linked to hydroxyburpropion, Journal of Controlled Release 113 (2006) 137-145	
	95	KIRKHAM et al. "Psychopharmacology 153:267-270(2001)	
	96	Leppik et al. Epilepsy Research; 14:165-173 (1993).	
	97	LESSIG, et al., "Topiramate for Reversing Atypical Antipsychotic Weight Gain" J. Am. Child Adolesc. Psychiatry 40;12 December 2001. p 1364.	
	98	LEVY, et al., "Topiramate Produced Weight Loss Following Olanzapine-Induced Weight Gain in Schizophrenia" J. Clin. Psychiatry 63;11 November 2002, 1045.	
	99	Matsuura, "Indication for Anterior Temporal Lobectomy in Patients with Temporal Lobe Epilepsy and Psychopathology", Epilepsia 41(Suppl. 9) :39-42 (2000)	
	100	McElroy et al. "Zonisamide in the Treatment of Binge-Eating Disorder: An Open-Label, Prospective Trial." J. Clin. Psychiatry; 65(1):50-56 (2004).	
	101	McElroy et al. Inpharma; 1428:10 (2004)	
	102	MCLAUGHLIN, et al, " Behavioral Pharmacology, 14:583:588 (2003)	
	103	Morris, III, "The Effect of Zonisamide Administration on Patient Weight", A Scientific Exhibit at the American Epilepsy Society Annual Meeting, December 3, 2000, Los Angeles, California	
	104	NAVARRO, et al. "Topiramate for Clozapine-Induced Seizures" Am. J. Psychiatry 158; 6, June 2001, 968-969	
	105	NDA20-789, ZONEGRAN (zonisamide) Capsules 100 mg, FDA Approved Labeling Text, p1-24 (March 27, 2000).	
	106	PASTERNAK et al. J. of Med. Chem., 23:674-676 (1980)	

Examiner Signature	Date Considered
--------------------	-----------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	10/828,795
	Filing Date	April 21, 2004
	First Named Inventor	Weber, et al.
	Art Unit	1614
(Multiple sheets used when necessary)	Examiner	Zhang, Nancy
SHEET 6 OF 6	Attorney Docket No.	OREX.001A

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	107	PAVULURI, et al., "Topiramate Plus Risperidone for Controlling Weight Gain and Symptoms in Preschool Mania, Journal of Child and Adolescent Psychopharmacology vol. 12 Number 3, 2002. p. 271-273	
	108	POTTER, et al. "Sustained Weight Loss Associated with 12-month topiramate Therapy" Epilepsia, Raven Press Ltd. New York, vol 38, No. Suppl 8, 1997, Page 97	
	109	ROWLAND, et al. "Psychopharmacology, 159:111-116(2001)	
	110	Sackellares et al. Epilepsia; 26(3):206-211 (1985).	
	111	Schmidt et al. Epilepsy Research; 15:67-73 (1993).	
	112	Shapiro et al. "Additive Benefits of Combination Therapy with Sibutramine and Rimonabant on Body Weight, Insulin Sensitivity and Lipoproteins in Diet-Induced Obese Mice," 2005 NAASO Annual Meeting, Poster 405-P	
	113	Shapira et al. "Treatment of Binge-Eating Disorder with Topiramate: A Clinical Case Series." J. Clin. Psychiatry; 61(5):368-371 (2000).	
	114	SHELTON, Richard C., "Classification of Antidepressants and their Clinical Implications" Primary Care Companion J. Clin. Psychiatry 2003-5 (Supp. 7) pp. 27-32	
	115	THEARLE, et al. "Obesity and Pharmacology" Endocrinology and Metabolism Clinics of North American" W.B. Saunders Company, Philadelphia US Vol 32, No. 4, pp. 1005-1024. (2003)	
	116	Wadden et al. "Effects of Sibutramine Plus Orlistat in Obese Women Following 1 Year of Treatment by Sibutramine Alone: A Placebo-Controlled Trial," Obesity Research; 8(6):431 (2000).	
	117	Walker et al, "Chronic Toxicity of the Anticonvulsant Zonisamide in Beagle Dogs", Fundamental and Applied Toxicology 11:333-342 (1988)	
	118	WANG, et al., "Gabapentin augmentation therapy in bipolar depression" Bipolar Disorders 2002, 4; 296-301.	
	119	Welty et al, "Weight Loss Associated With Use of Zonisamide in European and US Clinical Trials", A Compendium of Posters and Platform Sessions for Zonegran®, Presented at the Annual Meeting 2001 of the American Epilepsy Society, November 30 – December 5, 2001, Philadelphia, Pennsylvania	
	120	Wilding. Current Drug Targets; 5:325-332 (2004).	
	121	Wilner, "Is Weight Loss With Zonisamide Gender-Specific?", Dr. Tran, 2002 Annual Meeting of the American Epilepsy Society, <a href="https://secure.neurohub.net/cgi-perl/get.cgi?pub=52318&amp;ext=htm">https://secure.neurohub.net/cgi-perl/get.cgi?pub=52318&amp;ext=htm</a>	

2985037  
100306

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.